REMARKS

Status of the Claims

Claims 5-9 are pending in this application. No claims have been canceled or added. Claim 1 has been amended to recite the specific group of monoclonal antibodies. Support for this amendment is found on page 6 of the specification. No new matter has been added by the above claim amendments.

Rejection under 35 USC 103(a)

The Examiner rejects claims 5-9 as obvious over Aoki et al. in view of Kohler. Applicants traverse the rejection and respectfully request the withdrawal thereof.

Present Invention

The present invention is directed to an immunoassay of a human medullasin comprising immobilizing human medullasin in a test sample by sandwiching the human medullasin between an anti-human medullasin monoclonal antibody immobilized on an insoluble carrier and a labeled anti-human medullasin monoclonal antibody by antigen-antibody reactions to form a complex, where the anti-human medullasin monoclonal antibody is at least one selected from a

group consisting of designated 3F03, 3G03, 2E04 and 1G12; and quantifying the label in the complex.

The anti-human medullasin monoclonal antibody originates from a mouse and is obtained by culturing hybridomas prepared by cell fusion between antibody-producing cells recovered from the mouse immunized with human medullasin and myeloma cells, to specifically recognize the human medullasin recovered from the culture.

Moreover, the present invention, as demonstrated by Example 2, has a one hour time period (the total time required for the incubations, 30 minutes for the first incubation and 30 minutes for the second incubation) to measure the medullasin. The results produced by the short assay are highly accurate. See for example, the calibration chart of Figure 1, which shows a well-correlated relationship with concentration, scattering to only a limited extent.

Applicants also submit that a deposit of a hybridoma will be made under the Budapest Treaty in Japan upon the allowance of claim 5. At such time, the specification will also be amended and a declaration submitted stating that no new matter has been added by the amendments to the specification reciting information relating to the Budapest Treaty deposit.

Distinguishing the Present Invention

Aoki et al. discloses an enzyme-aided immunoassay for quantitatively analyzing human medullasin in the blood by the aid of a polyclonal antibody (See page 195). Aoki et al. uses a polyclonal antibody for the quantitative analysis of human medullasin in the blood. The method disclosed in Aoki takes a total of 18 hours to complete, as described in Clinica Chimika Acta, volume 178, the last 2 lines on page 195 to line 11 in page 196. Two hours is required for the first incubation step for reacting IgG immobilized on polystyrene beads with medullasin in the blood, and 16 hours is required for the second incubation step for the medullasin polyclonal antibody conjugate.

Aoki et al. fails to disclose or suggest substituting a monoclonal antibody with a polyclonal antibody. The specific group of monoclonal antibodies is not disclosed nor suggested by Aoki et al. Aoki et al. also fails to disclose or suggest shortening the incubation times for arriving at the present invention as explained in the Reply filed on October 15, 2002 in the chart entitled, "Comparison with the Present Invention and Aoki et al."

Kohler discloses a basic process for producing monoclonal antibodies. Kohler does not disclose or suggest using a monoclonal

antibody in an immunoassay as recited in the present claims. Kohler also fails to disclose or suggest the specific group of monoclonal antibodies recited in the claims.

Neither Kohler nor Aoki discloses substituting monoclonal antibodies for the assay disclosed in Aoki. Neither Kohler nor Aoki discloses or suggests anti human medullasin monoclonal antibodies, such as 3F03, 3G03, 2E04 and 1G12. Furthermore, neither Kohler nor Aoki discloses arriving at the present invention of an immunoassay that produces results within one hour.

No Prima Facie Obviousness

Applicants submit that the Examiner has failed to establish a prima facie case of obviousness, because the Examiner has failed to show that one of ordinary skill in the art would be motivated to combine the teachings of Aoki et al with Kohler to arrive at an immunoassay that is capable of producing results within one hour and that uses monoclonal antibodies of the present invention.

In the absence of some teaching to combine the references or that there is some likelihood of arriving at the present invention from a combination of the two references, Applicants submit that the rejections should be withdraw as no prima facie case of obviousness has been established.

Conclusion

As Applicants have addressed and overcome all rejections in the Office Action, Applicants respectfully request that the rejections be withdrawn and that the claims be allowed. Should there be any outstanding matters that need to be resolved in the present application, the Examiner is respectfully requested to contact Kecia Reynolds (Reg. No. 47,021) at the telephone number of the undersigned below, to conduct an interview in an effort to expedite prosecution in connection with the present application.

Pursuant to 37 C.F.R. §§ 1.17 and 1.136(a), Applicant(s) respectfully petition(s) for a two (2) month extension of time for filing a reply in connection with the present application, and the required fee of $410.00 is attached hereto.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees

required under 37 C.F.R. §§ 1.16 or 1.17; particularly, extension of time fees.

Respectfully submitted,

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